



UNITED STATES DEPARTMENT OF COMMERCE
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JMI

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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10-10-1980

EXAMINER

HOUGHTON, S.

ART UNIT

PAPER NUMBER

DATE MAILED:

10-10-1980

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No
09/225,904

Applicant(s)

Sidransky et al.

Examiner

Scott Houtteman

Group Art Unit

1656



Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) 1-11 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

X Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-11 are indefinite in the recitation a method of treating a disorder "associated with 5'ALT polynucleotide" and "p16 expression product". The nature of the "association" is undefined and is unclear. Furthermore, since the steps of the treatment depend on the type of "association," the steps of the method are unclear.

If, for example, "associated" with 5'ALT means "encoding" 5'ALT then the method of treatment would involve some sort of efforts to mitigate the damaging effects of the 5'ALT gene expression. On the other hand, "associated with 5'ALT" could mean that the disorder is caused by a protein what fails to properly interact with 5'ALT, for example a mutant transcription activation factor. In this case, the treatment may not involve 5'ALT in any way, but rather efforts to replace the lost activation activity provided by another protein or perhaps to repair the activator binding site in the 5'ALT cis regulatory region.

Similarly, with respect to p16, the nature of the term "product" in the limitation "expression product" is unclear. It is not clear whether an "expression product" is mRNA, protein, enzyme or a particular enzymatic activity.

B. Claims 1-11 are indefinite in the recitations "5'ALT polynucleotide(s)" and p16 expression. The scope of these reagent limitations is unclear. Claim 1, for example, is drafted using the "(s)" suffix on the word polynucleotide which usually means either one or more than

claimed. If there is more than one, say for example a group of 5'ALT polynucleotides, then it is unclear what relationship exists among this group of 5'ALT polynucleotides and it is unclear how far the sequence of a member of this group can vary and still be a member of the group of

5'ALT polynucleotides. The same concerns apply the recitation of "p16." It is unclear how far one can vary from the p16 sequence explicitly disclosed in the specification and still be considered a "p16 expression product."

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-11 are drawn to methods of gene therapy and products used in these methods. The specification does not disclose how one readily identifies these associated "disorders." The specification does not offer extensive guidance on working models of treating disorders "associated with 5'ALT" and with "p16."

Additionally, the field of treating disorder, for example by inhibition of gene expression is very unpredictable as evidenced by Stolberg, "Despite Ferment, Gene Therapy Progresses," New

to deliver genes to their target cells." Rather than describing the field as predictable, this article makes clear that gene therapy is still seeing this glimpse of hope that this new technology is going to bear fruit in the clinic, and yet we have had this serious setback" referring to the unexpected death of a patient in a gene therapy clinical trial.

Lacking specific guidance into the methods of identifying a reasonable number of 5' ALT and p16 "disorders," and lacking a specific example of the treatment of any disorder, and in view of the highly unpredictable nature of the field, it would require undue experimentation to enable a reasonable number of the claimed embodiments.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the reasons set forth on the attached Notice to Comply With Requirements For Patent Applications Containing Nucleotide And/Or Amino Acid Sequence Disclosures. In responding to this Notice, Applicant is requested to return a copy of the attached Notice to Comply.

IN THE INTERESTS OF COMPACT PROSECUTION, AN ACTION ON THE MERITS HAS BEEN ISSUED. COMPLIANCE WITH THE SEQUENCE RULES, 37 C.F.R. 1.821-25, IS REQUIRED, IN ADDITION TO A RESPONSE TO THIS OFFICE ACTION, WITHIN THE THREE (3) MONTH SHORTENED STATUTORY PERIOD. FAILURE TO COMPLY WITH THESE REQUIREMENTS WILL RESULT IN ABANDONMENT OF THE APPLICATION UNDER 37 C.F.R. 1.821(g).

4. Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the *Official Gazette* of the United States Patent and Trademark Office, dated 1/6/00. The address is:

Serial No. 09 225.904
Art Unit 1656

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott Houtteman whose telephone number is (703) 308-3885. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

Scott Houtteman
June 19, 2000



**SCOTT W. HOUTTEMAN
PRIMARY EXAMINER**